Part of #23

Attorney's Docket No. PA-5047-FWC **PATENT**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Timothy A. Chuter
Serial No.: 08/ 159,774 Group No.: 3308
Filed: Nov. 30, 1993 Examiner: D. Brittingham
For: EXPANDABLE TRANSLUMINAL GRAFT PROSTHESIS FOR REPAIR OF ANEURYSM AND METHOD OF IMPLANTING

Commissioner of Patents and Trademarks
Washington, D.C. 20231

DECLARATION OF PRIOR INVENTION IN THE UNITED STATES TO OVERCOME CITED PATENT OR PUBLICATION (37 CFR 1.131)

PURPOSE OF DECLARATION

1. This declaration is to establish completion of the invention in this application in the United States at a date prior to August 22, 1991, that is the effective date of the prior art:

☒ publication Inoue WO 91/12047
☐ patent

that was cited by the

☒ examiner.
☐ applicant.

NOTE: *"(a) When any claim of an application or a patent under reexamination is rejected on reference to a domestic patent which substantially shows or describes but does not claim the rejected invention, or on reference to a foreign patent or to a printed publication, and the applicant or the owner of the patent under reexamination shall make oath or declaration as to facts showing a completion of the invention in this country before the filing date of the application on which the domestic patent issued, or before the date of the foreign patent, or before the date of the printed publication, then the patent or publication cited shall not bar the grant of a patent to the applicant or the confirmation of the patentability of the claims of the patent, unless the date of such patent or printed publication be more than one year prior to the date on which the applicant's or patent owner's application was filed in this country." 37 CFR 1.131(a).*

NOTE: *37 CFR 1.131 is not applicable to a rejection based on a U.S. patent which CLAIMS the rejected invention.*

CERTIFICATE OF MAILING/TRANSMISSION (37 CFR 1.8(a))

I hereby certify that this correspondence is, on the date shown below, being:

MAILING

☒ deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to the Commissioner of Patents and Trademarks, Washington, D.C. 20231

FACSIMILE

☐ transmitted by facsimile to the Patent and Trademark Office

Barbara J. Forss
Signature
Barbara J. Forss
(type or print name of person certifying)

Date: Dec. 14, 1994

2. The person making this declaration is (are):

- ☒ the inventor(s).
- ☐ only some of the joint inventor (*and a suitable excuse is attached for failure of the omitted joint inventor(s) to sign*).
- ☐ the party in interest (*and a suitable explanation as why it is not possible to produce the declaration of the inventor(s) is attached*).

FACTS AND DOCUMENTARY EVIDENCE

3.

NOTE: "The affidavit or declaration must state FACTS and produce such documentary evidence and exhibits in support thereof as are available to show conception and completion of invention IN THIS COUNTRY at least the conception being at a date prior to the effective date of the reference." MPEP § 715.07.

To establish the date of completion of the invention of this application the following attached documents and/or models are submitted as evidence:

(check all applicable items below)

- ☐ sketches
- ☐ blueprints
- ☐ photographs
- ☒ reproduction(s) of notebook entries — See supporting statement by Inventor
- ☐ model
- ☐ supporting statement(s) by witness(s) (where verbal disclosures are the evidence relied upon)

NOTE: While conception is the mental part of the inventive act, it must be capable of proof, such as by demonstrative evidence or by a complete disclosure to another. Conception is more than a vague idea of how to solve a problem. The requisite means themselves and their interaction must also be comprehended. See Mergenthaler v. Scudder 1897 C.D. 724, 81 O.G. 1417." MPEP § 715.

From these documents and/or models it can be seen that the invention in this application was made

- ☐ on _____
- ☒ at least by the date of Aug. 21, 1991, which is a date earlier than the effective date of the reference.

NOTE: "If the dates of the exhibits have been removed or blocked off, the matter of dates can be taken care of in the body of the oath or declaration." MPEP § 715.07.

NOTE: "The dates in the oath or declaration may be the actual dates, or, if the applicant or patent owner does not desire to disclose his or her actual dates he or she may merely allege that the acts referred to occurred prior to a specified date." MPEP § 715.07.

DILIGENCE

NOTE: *"Where there has not been reduction to practice prior to the date of the reference, the applicant or patent owner must also show diligence in the completion of his or her invention from a time just prior to the date of the reference continuously up to the date of the actual reduction to practice or up to the date of filing his or her application (filing constitutes a constructive reduction to practice, § 1.131)."* MPEP § 715.07 (emphasis added).

NOTE: *"A conception of an invention, though evidenced by disclosure, drawings, and even a model, is not a complete invention under the patent laws, and confers no rights on an inventor, and has no effect on a subsequently granted patent to another, UNLESS HE OR SHE FOLLOWS IT WITH REASONABLE DILIGENCE BY SOME OTHER ACT, such as an actual reduction to practice or filing an application for a patent. Automatic Weighing Mach. Co. v. Pneumatic Scale Corp., Limited 1909 C.D. 498, 139 O.G. 991.*

"Conception in the mental part of the inventive act, but it must be capable of proof, as by drawings, complete disclosure to another person, etc. In Mergenthaler v. Scudder, 1897 C.D. 724, 81 O.G. 1417, it was established that conception is more than a mere vague idea of how to solve a problem; the means themselves and their interaction must be comprehended also." MPEP § 715.07.

NOTE: *Only diligence before reduction to practice is a material consideration. The "lapse of time between the completion or reduction to practice of an invention and the filing of an application thereon" (Ex parte Merz 74 USPQ 296) is not relevant to an affidavit or declaration under 37 CFR 1.131.* MPEP § 715.07(a).

Attached is a statement establishing diligence of the applicants from the time of their conception to a time just prior to the date of the reference up to the:

- ☐ actual reduction to practice.
- ☐ filing of this application.

TIME OF PRESENTATION OF THE DECLARATION

(complete (a), (b) or (c))

(a) ☒ This declaration is submitted prior to final rejection.

(b) ☐ This declaration is submitted with the first response after final rejection and is for the purpose of overcoming a new ground of rejection or requirement made in the final rejection.

(c) ☐ This declaration is submitted after final rejection and a showing under 37 CFR 1.116(b) is submitted herewith.

DECLARATION

6. As a person signing below:

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

SIGNATURE(S)

7. (complete A or B below)

A. Inventor(s)

Full name of ~~sole~~ or ~~first~~ inventor Timothy A. Chuter

Inventor's signature Timothy A. M. Chuter.

Date 11/30/94 Country of Citizenship ~~U.S.A.~~ BRITAIN

Residence ~~Pittsford, New York~~ IRVINGTON, NEW YORK.

Post Office Address ~~65A Main Street~~ 44 TAXTER ROAD

~~Pittsford, New York 14534~~ IRVINGTON NEW YORK 10533.

Full name of **second** joint inventor, if any _____

Inventor's signature _____

Date _____ Country of Citizenship _____

Residence _____

Post Office Address _____

(use added page for signature by additional inventors)

Number of pages added: _____

B. Assignee

_____
type or print name of person signing

_____
Signature

_____
Date

_____
P.O. Address

_____

_____
(type name of assignee)

_____
Address of assignee

_____

_____

_____
Title of person authorized to sign on behalf of assignee

Assignment recorded in PTO on _____

Reel _____ **Frame** _____

A "CERTIFICATE UNDER 37 CFR 3.37(b)" is attached.

Serial No. 08/159,774

PATENT

SUPPORTING STATEMENT BY INVENTOR

Enclosed herewith are reproductions of entries made by myself in a bound laboratory notebook to establish the date of completion of the invention of this application on or before August 21, 1991, which is a date earlier than the effective date of the Inoue reference, document number WO 91/12047. The dates of the actual entries have been blocked off from the reproductions of the notebook entries, but are before August 21, 1991. These notebook entries on pages 7-15 document clinical trials of the completed invention on two dogs. Sketches on pages 9, 11, and 15 of these notebook entries illustrate a transluminal arrangement for positioning a prosthesis assembly at a particular position on a wall of a lumen. The transluminal arrangement includes an introducer sheath with a bore extending therethrough and a prosthesis assembly positioned within the bore of the sheath for positioning the prosthesis assembly at a desired location within a blood vessel lumen. The prosthesis assembly includes a graft and a self-expanding spring for radially expanding the graft to conform to the wall of a blood vessel lumen after the prosthesis assembly has been released from the introducer sheath. A pusher catheter is positioned within the bore of the catheter for retaining the prosthesis assembly at the desired position in the blood vessel lumen when withdrawing the introducer sheath from the self-expanding spring assembly. The pusher catheter includes an outer catheter with a wire centrally positioned therethrough. Holes are positioned within the walls of the catheter for positioning therethrough mooring loops that are attached to the prosthesis assembly. The mooring loops are maintained within the lumen of the outer catheter until the central wire is removed from the outer catheter. This transluminal arrangement was utilized in an intraluminal surgical procedure for delivering and positioning the prosthesis assembly in the aorta of two dogs on which I performed clinical trials. These trials were performed to evaluate the use of the transluminal arrangement and prosthesis assembly on human subjects.

11/30/94
Date

Timothy A. Chuter

(7)

All of these buttons are filled with resin and filed smooth; so that no lips or edges remain to catch on the prosthesis during removal.

First dog trial

50 lb female
Pentobarbital IV, after IP induction.
Femoral cut-down. Angiogram via femoral a.
→ Infra-renal aorta 4 cm long
Big lumbar branches
Must be more lumbar vertebrae in dog. Counting from a presumed L5 below the bifurcation is @ top of "L3" and the renal at the top of "T12". ??
Diameter of aorta ≈ 9 mm.
(R) femoral @ is = 4 mm.
The marked catheter did not work.
The markings were not radiodense enough.
Sizes were estimated by comparison to the diameter of a 5 F catheter (≈ 1.5 mm)
The aorta was 6× that.

(R) iliac exposed through Gibson incision/ retroperitoneal approach.
(R) common iliac = 6 mm.
Introducer 4 passed through transverse common iliac arteriotomy. 2,000 units heparin IV

The sheath plug did not ensure hemostasis in the face of arterial pressure.

Upper spring placed at upper end of "L1." Continual fluoroscopy. Insertion and extension of prosthesis took = 30s. Fluoro's on video #20 – 105. Images 58, 59, 60, 4, 5.

Angiograms confirmed position of upper spring relative to the renal vessels, and patency of lumen and position of lower spring relative to the iliac vessels. No leakage around the graft on angiogram or excision of Dacron graft aorta at explant. Lethal dose of pentobarbital. IV.

Post-mortem excision of graft and surrounding aorta.

Conclusion:

Need iliac insertion.

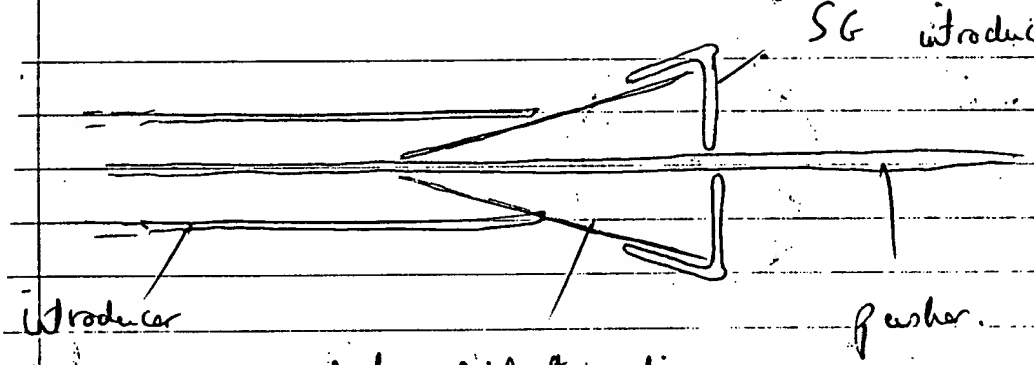
The graft is easy to place precisely and fixes in position securely.

The walls of the graft conforms well to the wall of the aorta with little impingement on the lumen, even in the region unsupported by springs.

Plan:

① Improve the sheath plug by the addition of a 5F cath introducer

⑨



Dual pipette tip

② Attempt aneurysm creation

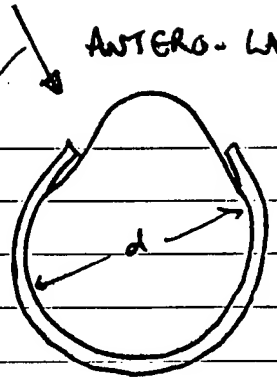
③ Manufacture
- 10 x 20 mL, 12 G prostheses.
- 2 x 4 F pushers - more rigid if pon. ↑ graduate these.

$1,000 paid to RGH for the 1st 2 dogs ie 7/17 and 7/19.

Dog 2.

Aorta exposed through flank incision with retroperitoneal approach.

4 cm incision of adventitia and media ~ 1/2 way between the renals and the iliac. Plane between media and intima directed. 2 mm of wall excised on either side of the incision. This portion of the aorta bulged in all directions, but most in the area where the outer layers had been removed.

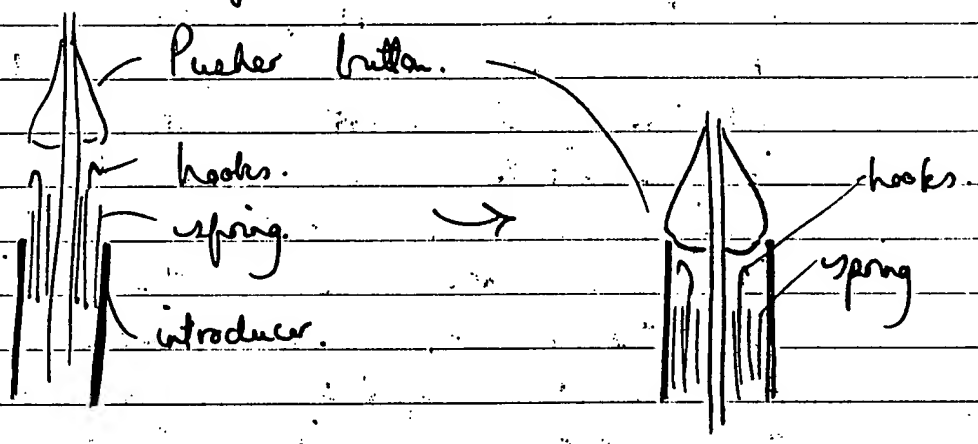


Angiogram showed the internal diameter (d) in the middle of the aneurysm to be ≈ 1½ x the diameter of the normal aorta, above and below. Absolute measurements are unreliable 2° magnification.

A small leaking point ceased bleeding with pressure alone.

Attempted insertion of the #18, 12G graft via the (L) iliac was unsuccessful due to an inability to remove the pusher. The pusher kept seemed to get caught at the upper spring/graft junction I think that the unsupported graft did not dilate sufficiently. I also suspect that this may have resulted from a failure of the upper spring to engage the entire aortic wall and direct all the blood down the lumen of the graft. Extra luminal flow would negate the dilating effect of arterial pressure on the central portion of the graft.

We also experienced difficulty inserting the introducer / prosthesis via the (L) iliac a. The graft was a little longer than that used on Wednesday (7 cm vs 5 cm) and could not be packed completely into the short end of the introducer. Switching to the longer end enabled the whole graft, springs and barbs to be enclosed.



A solution to both problems might be to abandon the pusher button and muzzle loading introducer, in favour of a dilator and breech loading introducer.

Advantages.

① A dilator is easy to remove

② The introducer sheath need not move forward except on the back of a dilator

These are most helpful when the introducer sheath is large rel and the vessels small (dog)

Disadvantages.

① Dilator tend to be rigid
② The graft cannot negotiate sharp curves within the confines of a tight introducer sheath.

These considerations present little problem in the dog model, with soft vessels and a narrow angle between iliac arteries. I expect that human work will necessitate a return to the more flexible muzzle loading version; perhaps with a balloon as the dilator button & the pusher. A balloon could, of course, be deflated before removal of the pusher, which would eliminate the problems this we had today in removing the pusher button.

NB The images are upside down (the dog's head was to the Ⓡ). They are stored on the hard drive as #6 and #7, and on the tape #110 to #135.

(13)

Some of the difficulty yesterday was 2° large introducer / small a. Arterial size seems to be variable, even in dogs of the same size.

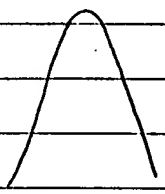
Would like to reduce introducer diameter < 5 mm.

Options include

① Thin graft - not available
② Smaller pusher
③ Spring that packs smaller.

The main limiter on ③ is the points of the spring - the radius of curvature has a range, depending upon the force applied and the gauge of wire. Very large forces are required to achieve the sharp points necessary for tight packing. That is why 12 G packs better than 16 G. Another alternative is to eliminate variability at this point by creating a compound curvature.

instead of

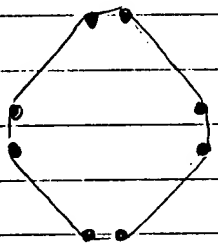


The current method of pusher attachment relies upon an open curve at the point because where the hooks engage

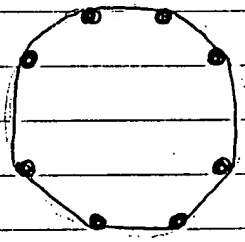
the spring.

Another disadvantage of the closed point is the narrower apex, at the open rim of the graft. A wide apex ensures a more even spacing of the spring arms, creating a more nearly circular orifice.

Closed point



Open point



A way to make the closed point work better is to have a larger portion of the spring outside the graft. This necessitates a longer spring arm. Perhaps 2½ cm rather than 2 cm.

The closed point spring seems to be more elastic. Can probably use larger gauge wire.

A different method of pusher attachment will be needed. Loops on the graft instead of points on the spring. Loops have the advantage that they can act as guy ropes throughout the whole range of graft size, without any movement of the pusher attachment site.

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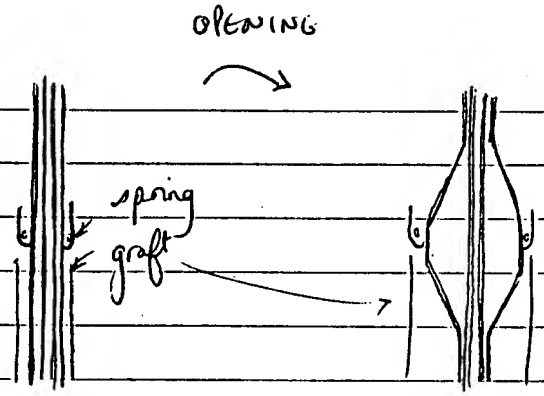
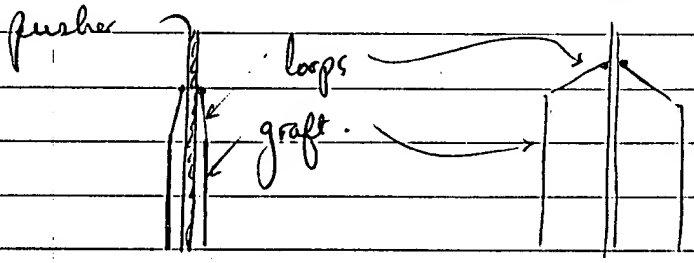


Current system.

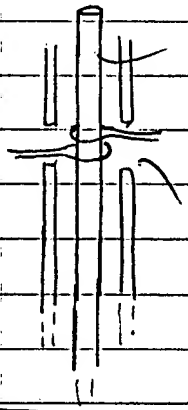


With loops.

the cantilever is not required.

To reduce size the loops could hook onto a slot in the top of a single shafted pusher.

A more secure method would involve a release mechanism under external control.



The loops would not release until the wire is withdrawn.